



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,928	06/29/2006	David James Squirrell	41577326422	9314
23370 7590 08/26/2009 JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET SUITE 2800 ATLANTA, GA 30309				
EXAMINER				
BHAT, NARAYAN KAMESHWAR				
ART UNIT		PAPER NUMBER		
1634				
MAIL DATE		DELIVERY MODE		
08/26/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/568,928

Applicant(s)

SQUIRRELL ET AL.

Examiner

NARAYAN K. BHAT

Art Unit

1634

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/23/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 18-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 25-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continued Examination under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 23, 2009 has been entered.

Claim Status

2. Claims 1-47 are pending in this application. Claims 1, 25, 36 and 40 have been amended. Claim amendments have been reviewed and entered.
3. Claims 18-24 were withdrawn without traverse from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention of group II and III and made final in the office action dated August 04, 2008.
4. Claims 1-17 and 25-47 are under examination.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-6, 8-9 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Koike et al (USPN 5,305,650 issued Apr. 6, 1994).

Claim 1 recites following structural components: (i) a movable platform comprising first and second chambers and a first functional component and (ii) an arm for raising and lowering the functional component. Koike et al teaches structural components (i) and (ii) as discussed below

Regarding structural component (i), Koike et al teaches an apparatus comprising a turntable 15, i.e., a moveable platform (Fig. 2, column 4, and line 35). Koike et al further teaches that the turn table comprises a sample container 18, i.e., first chamber suitable for receiving a sample (Fig. 2, column 4, lines 45-49). Koike et al also teaches a container 19 (i.e., a second chamber) into which an analyte extracted from the sample or a reagent may be delivered (Fig. 2, lines 49-52). Koike et al further teaches a probe needle 26, i.e., a first functional component (Fig. 1, column 5, lines 53-57), which is releasably held in place on the turntable and able to act as collector for moving the sample from container to another container on the turntable (Fig. 1, column 5, lines 29-51).

Regarding structural component (ii), Koike et al teaches an arm 33 capable of

being raised and lowered and removeably attached to the probe needle, i.e., a first functional component and further teaches that probe needle may be raised and lowered with the arm (Fig. 1, column 5, lines 53-67). Koike et al also teaches that the turntable is fixed on a rotating shaft 20 rotated by motor 22 and microcomputer for controlling the desired treatments (Fig. 3, column 2, lines 47-51 and column 5, lines 1-4), which is configured to align any chamber or probe needle (i.e., functional component) with respect to the arm.

Regarding claim 2, Koike teaches that the turntable, i.e., platform is circular (Fig. 1).

Regarding claim 3, Koike et al teaches that the probe needle 26 is attached and detached from the arm 33 (column 2, lines 28-31), which is reasonable interpreted as the arm mechanically removeably attaches to the functional component.

Regarding claim 4, Koike et al teaches that an arm can be raised or lowered in a substantial vertical direction (column 5, lines 53-67).

Regarding claim 5, Koike et al teaches that the probe needle (i.e., first functional component) is used to remove sample from the container (column 5, lines 29-52).

Regarding claim 6, Koike et al teaches that the containers, i.e., chambers comprise magnetic particles for mixing the sample (column 8, lines 20-23).

Regarding claims 8 and 9, Koike et al teaches the apparatus further comprises a magnet (column 8, lines 17-20).

Regarding claims 11-12, Koike et al teaches that the apparatus comprises a heating block capable of heating the contents of the chamber of the apparatus (column

3, lines 1-4).

Regarding claim 13, Koike et al teaches an ultrasonic oscillator, i.e., physical processor, capable of sonicating the contents of the container of the apparatus (column 8, lines 23-26).

7. Claims 36-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al (WO 01/11374 published Feb. 15, 2001).

Claim 36 recites following structural components a platform comprising: (i) a chamber, (ii) one or more additional chambers comprising reagents and (iii) a hole for engagement with a feature of a functional component. Clark et al teaches structural components (i) to (iii) as discussed below.

Regarding structural component (i), Clark et al teaches a reagent carousel, a platform (Fig. 1, # 4, pg. 35, line 9) comprising a sample receiving element comprising a channel, i.e., a chamber suitable for receiving a sample (Fig. 1, # 6, pg. 7, lines 27-29, pg. 34, line 12 and pg. 36, lines 25-29).

Regarding structural component (ii), Clark et al teaches a reagent well containing pre-dispensed reagents for use in the processing (Figs. 2A, # 8, pg. 35, lines 26-28) and further teaches chambers are sealed with a sealing label comprising piston I (Fig. 5A, piston # 24, sealing label # 22, pg. 37, lines 16-23).

Regarding structural component (iii), Clark et al teaches that the reagent well 8 has a hole and seal 22 for engagement with upper portion (i.e., a feature) of the piston 24 (i.e., a functional component) thereby supporting the functional component (Fig. 5A,

pg. 37, and lines 5-8).

Regarding claim 37, Clark teaches that the reagent carousel, i.e., platform is circular (Fig. 1, # 4).

Regarding claim 38, Clark et al teaches that the apparatus comprises reagent well, i.e., a chamber containing pre-dispensed reagents and is exchangeable (Fig. 2A, # 8, pg. 7, lines 25-34, pg. 35, lines 26-28).

Regarding claim 39, Clark et al teaches a barcode for identifying element of the cartridge, which includes chambers in the cartridge (pg. 21, lines 12-15).

8. Claims 36-38 and 40-47 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Squirrell (WO 2002/087762 filed April 18, 2002).

Claim 36 recites following structural components a platform comprising: (i) a chamber, (ii) one or more additional chambers comprising pre-dispensed reagents and (iii) a hole for engagement with a feature of a functional component. Squirrell teaches structural components (i) to (iii) as discussed below.

Regarding structural component (i), Squirrell teaches a platform for processing a sample prior to nucleic acid amplification reaction, the platform 32 (Fig. 6, pg. 15, lines 3-4) comprising a chamber 39 suitable for receiving a sample (Fig. 6, pg. 9, line 25).

Regarding structural component (ii), Squirrell teaches chambers 13 and 14 containing pre-dispensed reagents for use in the processing and further teaches chambers are sealed with a metal foil laminate sheet 45 (Fig. 6, pg. 6, lines 8-11, pg. 15, lines 15-20 and 30-31).

Regarding structural component (iii), Squirrell teaches a grab hole 31 in the lid 9 for engagement with a hole 9a feature of a plunger 4, (i.e., a functional component) to thereby support the functional component (Fig. 5, pg. 14, lines 29-35). Squirrell also teaches that the plunger 4 has a hole 9a for magnet 30 to support the plunger to attract magnetic particles bound to sample (i.e., a feature) to the plunger (pg. 16, lines 1-4). It is noted that grab hole 31 in the lid 9 or a hole 9a in the plunger 4 of Squirrell are the features supporting the functional component as claimed.

Regarding claim 37, Squirrell teaches that the housing 1 (i.e., platform) is circular (Fig. 3a).

Regarding claim 38, Squirrell teaches that the support 32 comprises plurality of chambers 34, 36 and 38 with pre-dispersed reagent for use in processing (Fig. 6).

Claim 40 recites following structural components a platform comprising: (a) a chamber, (b) one or more additional chambers and (c) a first functional component. Squirrell teaches structural components (a) to (c) as discussed below.

Regarding structural component (a), Squirrell teaches disposable unit (pg. 12, line 35) comprising a housing 1, i.e., a platform (Fig. 2, pg. 11, line 13, pg. 12, lines 32-34) comprising a chamber 10 suitable for receiving a sample (Fig. 2, pg. 13, lines 1-5).

Regarding structural component (b), Squirrell teaches a reagent well 11 containing pre-dispensed reagents for the processing operation (Figs. 2, pg. 13, lines 3-6).

Regarding structural component (c), Squirrell teaches a plunger 4, i.e., a first functional component (Fig. 6, pg. 15, lines 23-28), which is releasably held in place on

the platform such that it can be removed and replaced onto the platform and wherein the plunger 4 (i.e., first functional component) is configured to act as collector for moving the sample contained therein or the reagent from one chamber to the other (Fig. 6 and pg. 16, lines 1-36 and pg. 17, lines 1-14).

Regarding claim 41, Squirrell teaches that the support unit 32 (i.e., platform) is adapted to carryout processing operation on a single fluid sample (Fig. 6, pg. 15, lines 1-2).

Regarding claims 42 and 43, Squirrell teaches that chambers containing pre-dispensed reagents are sealed with metal seal 45 (Fig. 6, pg. 11, line 19 and pg. 15, lines 30-31).

Regarding claims 44 and 45, Squirrell teaches the plunger 4 comprises a sharp conical tip 4a (i.e., cutter) for puncturing the seal 18 (Fig. 1, pg. 12, lines 5-9).

Regarding claim 46, Squirrell teaches that the plunger 4 comprises a magnet 30 (i.e., separating material) for separating magnetic beads (i.e., solid phase material) from the sample (Fig. 6 and pg. 16, lines 1-8). Squirrell also teaches plunger 4 further comprises a wall (i.e., sheath) surrounding the hole 9a, which provides an interface between the magnet 30 and the magnetic beads (Fig. 5a).

Regarding claim 47, Squirrell teaches that the pre-dispensed reagents comprise pre-dispensed magnetic beads coated with antibodies for capturing target organisms i.e., solid phase binding material (pg. 13, lines 1-2, pg. 16, lines 1-19).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 5-7, 8, 10, 15-17, 25-27, 30-38 and 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike et al (USPN 5,305,650 issued Apr. 6, 1994) in view of Jang (USPGPUB 20030082565 filed Fe. 14, 2002).

Claim 10 is dependent from claim 8, which is dependent from 6, which is dependent from 5, which is dependent from 1. Teachings of Koike et al regarding claims 1, 5, 6 and 8 are described above in section 6.

Regarding claim 7, Koike et al do not teach the solid phase binding material is silica.

Regarding claim 10, Koike et al teaches magnetic particles and magnet (column 8, lines 17-24). Magnetic particles of Koike et al solid phase material as defined in the instant claims 8 and 9. Koike et al do not teach first functional component is a sheath which provides an interface between the attracting material and the complex.

Regarding claims 15-17, Koike et al teaches that the predetermined amount of liquid is injected into the container (Fig. 13A, # S15 and S20, column 11, lines 5-35). Koike et al do not teach chamber comprising pre-dispensed reagent bound to the solid phase binding material.

Claim 25 recites following structural components: (i) a moveable platform, (ii) a chamber, (iii) a first functional component, (iv) a sealed chamber comprising pre-dispensed reagent and (v) an arm. Koike et al teaches structural components (i) to (v) except for the pre-dispensed reagent. Jang teaches chambers comprising pre-dispensed reagent as discussed below.

Regarding structural component (i), Koike et al teaches an apparatus comprising a turntable 15, i.e., a moveable platform (Fig. 2, column 4, and line 35).

Regarding structural component 'ii', Koike et al teaches that turn table comprises a sample container 18 (i.e., chamber) suitable for receiving a sample (Fig. 2, column 4, lines 45-49), wherein chamber is removable from the platform (column 2, lines 5-10) .

Regarding structural component 'iii' Koike et al teaches a probe needle 26, i.e., a first functional component (Fig. 1, column 5, lines 53-57) capable of moving an analyte or reagent or piercing seals of chambers that may reversibly attach to an arm of the apparatus and that may be held on the turntable (i.e., platform) such that it can be

removed from and replaced onto the turntable (Fig. 1, column 2, lines 23-30 and 57-60, column 7, lines 15-20).

Regarding structural component 'iv', Koike et al teaches a sealed chamber (column 7, line 8) and further teaches that the predetermined amount of liquid is injected into the container on the turntable (Fig. 13A, # S15 and S20, column 11, lines 5-35). Koike et al do not teach a sealed chamber comprising pre-dispensed reagent.

Regarding structural component (v), Koike et al teaches an arm 33 capable of being raised and lowered and removeably attached to the probe needle, i.e., a functional component and further teaches that probe needle may be raised and lowered with the arm (Fig. 1, column 5, lines 53-67). Koike et al also teaches that the turntable is fixed on a rotating shaft 20 rotated by motor 22 and microcomputer for controlling the desired treatments (Fig. 3, column 2, lines 47-51 and column 5, lines 1-4), which is configured for aligning any chamber or probe needle (i.e., functional component) with respect to the arm.

Regarding claim 26, Koike teaches that the turntable, i.e., platform is circular (Fig. 1).

Regarding claim 27, Koike et al teaches chambers from the reagent stations 66 and 67 are moved to turntable and back to reagent station a sealing mechanism for defining a sealing chamber (Figs. 2 and 13B # S29, column 7, lines 15-20 and column 8, lines 53-58), thus teaching an exchangeable chamber. Koike et al do not teach an exchangeable chamber comprising pre-dispensed reagent.

Regarding claim 30, Koike et al teaches that the probe needle 26 is attached and

detached from the arm 33 (column 2, lines 28-31), which is reasonable interpreted as the arm mechanically removeably attaches to the functional component.

Regarding claim 31, Koike et al teaches that the probe needle (i.e., functional component) is used to remove sample from the container (column 5, lines 29-52).

Regarding claims 32 and 33, Koike et al teaches that the apparatus comprises a heating block capable of heating the contents of the chamber of the apparatus (column 3, lines 1-4).

Regarding claim 34, Koike et al teaches an ultrasonic oscillator, i.e., physical processor, capable of sonicating the contents of the container of the apparatus (column 8, lines 23-26).

Regarding claim 35, Koike et al teaches introducing the sample into the container in the apparatus (Fig. 13A # S10, column 10, lines 62-65).

Claim 36 recites following structural components a platform comprising: (i) a chamber, (ii) one or more additional chambers comprising pre-dispensed reagents and (iii) a hole for engagement with a feature of a functional component. Koike et al teaches structural components (i) to (iii) except for the pre-dispensed reagent. Jang teaches chambers comprising pre-dispensed reagent as discussed below.

Regarding structural component (i), Koike et al teaches a turntable 15, i.e., a platform (Fig. 2, column 4, and line 35) comprising a sample container 18 (i.e., chamber) suitable for receiving a sample (Fig. 2, column 4, lines 45-49).

Regarding structural component (ii), Koike et al teaches a container 19 (i.e., additional chamber) and further teaches that the chamber is a sealed chamber (column

7, line 8). Koike et al further teaches that the predetermined amount of liquid is injected into the container on the turntable (Fig. 13A, # S15 and S20, column 11, lines 5-35).

Koike et al do not teach a sealed chamber comprising pre-dispensed reagent.

Regarding structural component 'iii' Koike et al teaches a hole 42a for engagement of fingers 44a and 44b (i.e., a first functional component) to thereby support the fingers (Fig. 6, column 6, lines 25-46).

Regarding claim 37, Koike teaches that the turntable, i.e., platform is circular (Fig. 1).

Regarding claim 38, Koike et al teaches chambers from the reagent stations 66 and 67 are moved to turntable and back to reagent station a sealing mechanism for defining a sealing chamber (Figs. 2 and 13B # S29, column 7, lines 15-20 and column 8, lines 53-58), thus teaching an exchangeable chamber. Koike et al do not teach an exchangeable chamber comprising pre-dispensed reagent.

Claim 40 recites following structural components a platform comprising: (a) a chamber, (b) one or more additional chambers and (c) a first functional component. Koike et al teaches structural components (a) to (c) except for the pre-dispensed reagent. Jang teaches chambers comprising pre-dispensed reagent as discussed below.

It is noted that the platform is defined as "disposable". However none of the structural components of the claimed platform are defined by any special structure that define a disposable property or composition.

Regarding structural component (a), Koike et al teaches a turntable 15, i.e. a

platform (Fig. 2, column 4, and line 35) for carrying out a processing operation on a fluid sample further comprising a sample container 18 (i.e., chamber) suitable for receiving a sample (Fig. 2, column 4, lines 45-49).

Regarding structural component (b), Koike et al teaches a container 19 (i.e., additional chamber) and further teaches that the chamber is a sealed chamber (column 7, line 8). Koike et al further teaches that the predetermined amount of liquid is injected into the container on the turntable (Fig. 13A, # S15 and S20, column 11, lines 5-35). Koike et al do not teach a sealed chamber comprising pre-dispensed reagent.

Regarding structural component (c), Koike et al teaches a probe needle 26, i.e., a first functional component (Fig. 1, column 5, lines 53-57), which is releasably held in place on the turntable and able to act as collector for moving the sample from container to another container on the turntable (Fig. 1, column 5, lines 29-51).

Regarding claim 41, Koike et al teaches that the turntable 15 (i.e., platform) is adapted to carryout processing operation on a single fluid sample (Fig. 13).

Regarding claims 42 and 43, Koike et al teaches a sealed chamber (column 7, line 8) and further teaches membrane (column 12, line 33). Koike et al do not teach chamber comprises pre-dispensed reagent and chambers are sealed by membrane or metal seal.

Regarding claims 44 and 45, Koike et al teaches probe needle comprises a tip 309 (i.e., second functional component) for inserting into the inner lid 313 of the vessel 311 (Fig. 19, column 13, lines 37-45), thus teaching second functional component interacting with the chamber and comprises a cutter.

Regarding claims 46 and 47, Koike et al teaches magnetic particles and magnet (column 8, lines 17-24). Magnetic particles of Koike et al solid phase material as defined in the instant claims 8 and 9. Koike et al do not teach first functional component comprises separating material for separating a solid phase material from the sample and further comprises a sheath which provides an interface between the separating material and the solid phase material. Koike et al do not teach pre-dispensed reagent comprises a processing reagent bound to a solid phase binding material.

As described above Koike et al do not teach sealed container comprising pre-dispensed reagents. However, sealed container comprising pre-dispensed reagents were known in the art at the time of the claimed invention was made as taught by Jang.

Jang teaches an apparatus for isolating nucleic acids comprising a plurality of sealed chamber 15 further comprising pre-dispensed reagents for sample processing before nucleic acid amplification (Fig. 2, paragraph 0023).

Regarding claim 7, Jang teaches silica (paragraph 005, line 3).

Regarding claim 10, Jang teaches an apparatus 300 for isolating nucleic acids comprising a magnetic bar 30 (i.e., first functional component) for attracting solid materials and the complex in the chamber 15 through a bore 24 (Fig. 6, paragraphs 0038-0043). Bore 24 which cover the magnet 30 is reasonably interpreted as sheath.

Regarding claims 15-17, Jang teaches that the chamber comprises pre-filled (i.e., pre-dispensed) reagents and solid materials for processing sample before nucleic acid amplification (paragraphs 0013-0015).

Regarding claims 25, 27, 36, 38, 40 and 42, Jang teaches that the chambers

comprising pre-dispensed reagent for use in processing fluid sample are sealed (paragraph 0034).

Regarding claim 43, Jang teaches that the sealing material is aluminum metal seal (paragraph 0034).

Regarding claim 46, Jang teaches an apparatus 300 for isolating nucleic acids comprising a magnetic bar 30 (i.e., first functional component) for separating a solid phase material from the sample (Jang, claims 28 and 29). Jang also teaches a bore 24 through which magnet bar passes through (Fig. 6, paragraphs 0038-0043). Bore 24 which cover the magnet 30 is reasonably interpreted as sheath.

Jang also teaches pre-dispensed reagents in a sealed chamber are inexpensive and effective in sample manipulations and avoiding manual pipetting by a person who is not fully trained and directly transferring nucleic acids isolated from sample for PCR amplification (paragraph 0044).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to apply the pre-dispensed reagents in the sealed chamber of Jang in the apparatus of Koike et al with a reasonable expectation of success with the expected benefit of having pre-dispensed reagents in a sealed chamber, which are inexpensive and effective in sample manipulations and avoiding manual pipetting by a person who is not fully trained and directly transferring nucleic acids isolated from sample for PCR amplification as taught by Jang (paragraph 0044).

12. Claims 1 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Koike et al (USPN 5,305,650 issued Apr. 6, 1994) in view of Lee (WO 98/24548 published Jun. 11, 1998, cited in IDS filed 3/27/2006).

Claim 14 is dependent from claim 1. Teachings of Koike et al regarding claim 1 are described above in section 6.

Regarding claim 14, Koike et al teaches a plurality of container but do not teach about the chamber coated with electrically conducting polymer. However, coating of the chamber with an electrically conducting polymer was known in the art at the time of the claimed invention was made as taught by Lee.

Lee teaches a reaction vessel, i.e., a chamber (Fig. 1, # 1) coated with an electrically conducting polymer (Fig. 1, # 3, pg. 11, lines 1-5). Lee also teaches that electrically conducting polymer coated reaction vessels provides an efficient system for rapid heating and cooling of reactions and temperature of the individual vessels is controlled independently of one another with their own profile for carrying out different reactions requiring different operating temperatures (pg. 5, lines 21-31).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to modify the container of Koike et al with chamber coated with an electrically conducting polymer of Lee with a reasonable expectation of success.

An artisan would have been motivated to modify the chamber of Clark et al with the expected benefit of having electrically conducting polymer coated reaction vessels providing an efficient system for rapid heating and cooling of reactions and having temperature of the individual vessels controlled independently of one another with their

own profile for carrying out different reactions requiring different operating temperatures as taught by Lee (pg. 5, lines 21-31).

13. Claims 25, 27-29, 36 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike et al (USPN 5,305,650 issued Apr. 6, 1994) in view of Jang (USPGPUB 20030082565 filed Fe. 14, 2002) as applied to claims 25 and 36 as above and further in view of Heath et al (USPGPUB 2004/0092731 filed Oct. 20, 1999).

Claims 28 and 29 are dependent from claim 27, which is dependent from claim 25. Claim 29 is dependent from claim 36. Teachings of Koike et al and Jang regarding claims 25, 27 and 36 are described above in section 11.

Regarding claims 28, 29 and 39, Koike et al and Jang do not teach chamber is marked with a bar code and a bar code reader. However, a bar code to mark the chamber and bar code reader were known in the art at the time of the claimed invention was made as taught by Heath et al.

Heath et al teaches an automated nucleic acid isolation apparatus comprising vessel 112 (i.e., chamber) marked with a barcode and further teaches the apparatus comprises bar code reader (paragraph 0080). Heath et al also teaches that the bar code on the chamber identifies the chamber and ensures that there is no contamination or cross-contamination with contents of other chamber or caps (paragraph 0085).

It would have been prima facie obvious to one having the ordinary skill in the art at the time the invention was made to apply the bar code on the chamber of Heath et al in the apparatus of Koike et al with a reasonable expectation of success with the

expected benefit of identifying the chamber and ensuring that there is no contamination or cross-contamination with contents of other chamber or caps as taught by Heath et al (paragraph 0085).

Response to remarks from the Applicants

Claim rejections under 35 U.S.C. § 102(b)

14. Applicant's arguments filed on April 27, 2009 with respect to claims 1-6, 11, 12, 15, 17, 25-33 and 40-45 as being anticipated by Clark et al have been fully considered (Remarks, pgs. 9-10), but are moot in view of withdrawn rejection and new grounds of rejection as set forth in this office action necessitated by claim amendments. Applicant's arguments regarding claims 36-39 as being anticipated by Clark et al have been fully considered and not found persuasive for the following reasons.

Applicants argue that in Clark et al the piston is housed within a well and supported on the upper seal of the well by adhesion but not by engagement with the hole (Remarks, pg. 10, paragraph 4). This argument is not persuasive because as described above in section 7, Clark et al teaches that the reagent well 8 has a hole and seal 22 for engagement with upper portion (i.e., a feature) of the piston 24 (i.e., a functional component) thereby supporting the functional component (Fig. 5A, pg. 37, and lines 5-8). Claim as recited merely requires a hole and the hole in the well taught by Clark meets the limitation of the claim. Applicant's arguments regarding dependent claims 37-39 are directed to claim 36 is not being anticipated by Clark (Remarks, pg. 10, last paragraph) and are not persuasive for the same reasons as described above.

Claim rejections under 35 U.S.C. § 103(a)

15. Applicant's arguments with respect to claims 1, 5-11, 13, 15, 16, 25, 32, 34, 40, 46 and 47 as being unpatentable over combination of references have been fully considered (Remarks, pg. 11), but are moot in view of withdrawn rejections and new grounds of rejection as set forth in this office action necessitated by claim amendments.

Conclusion

16. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Narayan K. Bhat whose telephone number is (571)-272-5540. The examiner can normally be reached on 8.30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Douglas) Schultz can be reached on (571)-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Narayan K. Bhat

Examiner, Art Unit 1634

/BJ Forman/

Primary Examiner, Art Unit 1634